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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,708	03/11/2005	Hideki Matsui	Q101073	9989

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	PAPER NUMBER
1633	

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12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,708	MATSUI ET AL.	
	Examiner	Art Unit	
	Fereydoun G. Sajjadi	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15,16,21,23-31,33,34,39 and 41-47* is/are pending in the application.

4a) Of the above claim(s) *1-13,16,21,23-31,33,34,39 and 41-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/11/2005 & 12/9/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of September 28, 2007, to the Restriction Requirement dated August 30, 2007 has been entered. No claims have been amended, cancelled or newly added.

Claims 41-47 were previously presented as new claims by the amendment dated March 11, 2005 with underlined text. 37 CFR 1.121(c) states: Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining. Please note that compliance with 37 CFR 1.121 is required for all future claim amendments. Failure to comply may result in non-entry of the amendment.

Claims 1-13, 15, 16, 21, 23-31, 33, 34, 39 and 41-47 are pending in the application.

Reassignment Affecting Application Location

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1633.

Election/Restrictions

Applicants' election of Group VIII (claim 15), drawn to a method for stimulating nerve growth comprising administering both an activating and a deactivating agent, is acknowledged. The election was made without traverse.

As the restriction is still deemed proper, the requirement for restriction is maintained and hereby made FINAL. Claims 1-13, 16, 21, 23-31, 33, 34, 39 and 41-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely responded to the restriction (election) requirement in the reply filed September 28, 2007.

Elected claim 15 is under current examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/9/2005 contains document no: 2002/034780, filed 3/21/2002 by Millennium Pharmaceuticals. However, no such document no. was found. It appears that the correct document no. should be 2002/0034780, that has been considered and indicated as such on form 1449. Should Applicants find the considered document to be in error, they may supply a new IDS with the correct document number for consideration by the examiner.

Claim Rejections - 35 USC § 112, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112~ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The instant claim broadly embraces a method for screening a compound or its salt using a polynucleotide encoding a protein or its partial peptide, comprising the same or substantially the same amino acid sequence as that represented by SEQ ID NO: 1, to inhibit gene expression and RNA expression of the variant proteins.

The specification states: "The amino acid sequence having substantially the same amino acid sequence as that represented by SEQ ID NO: 1 includes amino acid sequences having at least about 50% homology...to the amino acid sequence shown by SEQ ID NO: 1" [and]"include proteins having substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1 and having an activity of substantially the same nature as that of

the protein having the amino acid sequence represented by SEQ ID NO: 1, etc." (p. 8, lines 1-15). Thus, the protein comprising substantially the same amino acid sequence is not limited only to variants of SEQ ID NO: 1, as etc. includes an unspecified number of additional items. The specification additionally states that the protein includes a protein comprising the amino acid sequence represented by SEQ ID NOS: 6, 8, 10, 12, 14, 16, 18, 20, etc. (p. 8, lines 16-19). Further stating that activity of substantially the same nature include "a neurofibrillary degeneration promoting activity, a neural cell death promoting activity, and the like" (p. 8, lines 20-22). However, the specification is silent on any structure/function relationship for SEQ ID NO: 1 and its numerous claimed variants having "neurofibrillary degeneration promoting activity, a neuronal cell death promoting activity, and the like" (p. 8, lines 21-23). It is further unclear what variations are encompassed by SEQ ID NO: 1, etc. and SEQ ID NOS: 6, 8, 10, 12, 14, 16, 18, 20, etc., as the variations may include any amino acid changes or alterations at any position in SEQ ID NO: 1, as well as partial peptides of SEQ ID NO: 1, or sequences other than SEQ ID NO: 1, that retain an activity encompassing a neural cell death promoting activity and the like. The instant specification is silent on the specific alterations that distinguish SEQ ID NOS: 6, 8, 10, 12, 14, 16, 18, 20 from SEQ ID NO: 1, as all appear to encompass amino acid sequences of the same size and highly similar sequence to that of SEQ ID NO: 1, and are therefore not representative of the numerous variants encompassed by the claim.

The instant specification, while teaching the amino acid of human neuronal cell death inducible putative kinase (NIPK, SEQ ID NO: 1), and the base sequence of DNA encoding the same (SEQ ID NO: 2, p. 69), is silent on the numerous variants of polynucleotides encoding the proteins or partial peptides of SEQ ID NO: 1 variants, that display activities described as "a neurofibrillary degeneration promoting activity, a neural cell death promoting activity, and the like". Moreover, the numerous variant sequences, are not completely described in the prior art or the present specification.

The numerous sequence variants having neurofibrillary degeneration promoting activity, a neuronal cell death promoting activity, and the like, were not known at the time of the instant invention by Applicants, and include sequences yet to be discovered. The claims thus constitute a claimed genus that encompasses other protein sequences and their variants yet to be discovered

and analyzed for their ability to display the aforementioned biological activities, and since the specification only discloses the species of human NIPK protein (SEQ ID NOS: 1, 6, 8, 10, 12, 14, 16, 18, 20, that display neurofibrillary degeneration promoting activity, a neuronal cell death promoting activity, the numerous sequence variants claimed that display the same activities, or the like, do not constitute a substantial portion of the claimed genus.

Applicant's attention is also directed to *In re Shokal*, 113 USPQ 283 (CCPA 1957), wherein it is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 CCPA (Patents) 1309, 97 F2d 623, 38 USPQ 189; *In re Wahlforss*, 28 CCPA (Patents) 867, 117 F2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

As stated in MPEP 2163 II: If the application as filed does not disclose the complete structure (or acts of a process) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The instant specification is devoid of a description for the numerous variant proteins sequences that retain specific biological activities with respect to neurofibrillary degeneration promoting activity, a neuronal cell death promoting activity, or the like. The specification merely discloses the species of SEQ ID NOS: 1, 6, 8, 10, 12, 14, 16, 18, and 20. No other variant sequences displaying the requisite biological activities or the like are described. Thus, Applicants have failed to demonstrate possession of the numerous proteins claimed. Disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing "a result that one

might achieve if one made that invention"); In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). In the instant case, the disclosed biological function is further not limited to neurofibrillary degeneration promoting activity, a neuronal cell death promoting activity.

The disclosed structural features of SEQ ID NOS: 1, 6, 8, 10, 12, 14, 16, 18 and 20, do not constitute an adequate description to demonstrate possession of the numerous amino acid sequences claimed. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail such that the Artisan can reasonably conclude that the inventor(s) had possession of the claimed invention. Such possession may be demonstrated by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and/or formulae that fully set forth the claimed invention. Possession may be shown by an actual reduction to practice, showing that the invention was "ready for patenting", or by describing distinguishing identifying characteristics sufficient to show that Applicant was in possession of the claimed invention (January 5, 2001 Fed. Reg., Vol. 66, No. 4, pp. 1099-11).

Overall, what these statements indicate is that the Applicant must provide adequate description of such core structure and function related to that core structure such that the Artisan of skill could determine the desired effect. Hence, the analysis above demonstrates that Applicants have not described the numerous proteins that retain the requisite biological activities, and other undefined activities. As such, the Artisan of skill could not predict that Applicant possessed any additional species, except for that of SEQ ID NOS: 1, 6, 8, 10, 12, 14, 16, 18 and 20.

Therefore, the breadth of the claims as reading on numerous variant proteins that retain the required biological activities, as well as non-defined activities, including sequences, yet to be discovered; in view of the level of knowledge or skill in the art at the time of the invention, and the limited information provided in the specification, an Artisan of skill would not recognize

from the disclosure that Applicant was in possession of numerous growth factors, other factors and agents, at the time the application was filed.. Thus it is concluded that the written description requirement is not satisfied.

Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C.§112, first paragraph, because the specification, while being enabling for a method of screening for a compound or its salt that inhibits the expression of an RNA encoding a protein comprising the amino acid sequence set forth as SEQ ID NO: 1, said method comprising hybridizing an antisense molecule or ribozyme to RNA of a gene encoding a protein comprising the amino acid sequence set forth as SEQ ID NO: 1, thereby inhibiting the function of said RNA, does not reasonably provide an enablement for a method of screening a compound or its salt inhibiting the expression of a gene for a protein comprising the same or substantially the same amino acid sequence as the amino acid represented by SEQ ID NO: 1, which comprises using any polynucleotide encoding the protein or its partial peptide, as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is based on several issues related to the absence of an enabling disclosure for the ability to use any polynucleotide encoding a protein or partial peptide comprising substantially the same amino acid as that represented by SEQ ID NO: 1, to inhibit gene expression, that would include inhibition of promoter activity; or using variant antisense polynucleotides that would inhibit RNA expression. In determining whether Applicant's claims are enabled, it must be found that one of skill in the art at the time of invention by Applicant would not have had to perform "undue experimentation" to make and/or use the invention

claimed. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404:

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

MPEP § 2164.04 states: "[W]hile the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection."

The instant claim broadly embraces a method for screening a compound or its salt using a polynucleotide encoding a protein or its partial peptide, comprising the same or substantially the same amino acid sequence as that represented by SEQ ID NO: 1, to inhibit gene expression and RNA expression of the variant protein.

As a first issue, it should be noted that the inhibition of gene expression includes inhibition of promoter function either directly, or indirectly by inhibition of transcription factors. The instant specification, while teaching the amino acid of human neuronal cell death inducible putative kinase (NIPK, SEQ ID NO: 1), and the base sequence of DNA encoding the same (SEQ ID NO: 2, p. 69), fails to provide any information regarding the promoter sequences of genomic structure of the human NIPK gene. The specification if further silent on the transcription machinery controlling the expression of human NIPK, and additionally silent on how the transcription of the gene may be inhibited by using a polynucleotide encoding the protein of SEQ ID NO: 1, or its partial peptide, as no relationship between the amino acid sequences of SEQ ID NO: 1 and transcription machinery of the human NIPK gene has been established by either the Applicants or the prior art. Thus, a person of skill in the art would need to engage in further experimentation to discover and characterize the transcription machinery of the human NIPK gene and the sequences controlling promoter activity to design a compound screening method to discover inhibitors of the human NIPK transcription machinery based on the sequence or partial

peptide of SEQ ID NO: 1. Such experimentation thus constituting an undue burden on the skilled artisan.

As a second issue, the instant specification fails to describe the inhibition of RNA expression for a protein comprising substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1, comprising using a polynucleotide encoding a partial peptide of the protein. The specification states: "The amino acid sequence having substantially the same amino acid sequence as that represented by SEQ ID NO: 1 includes amino acid sequences having at least about 50% homology...to the amino acid sequence shown by SEQ ID NO: 1" [and]"include proteins having substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1 and having an activity of substantially the same nature as that of the protein having the amino acid sequence represented by SEQ ID NO: 1, etc." (p. 8, lines 1-15). The specification additionally states that the protein includes a protein comprising the amino acid sequence represented by SEQ ID NOS: 6, 8, 10, 12, 14, 16, 18, 20, etc. (p. 8, lines 16-19). Further stating that activity of substantially the same nature include "a neurofibrillary degeneration promoting activity, a neural cell death promoting activity, and the like" (p. 8, lines 20-22). However, the specification is silent on any structure/function relationship for SEQ ID NO: 1 and its numerous claimed variants having "neurofibrillary degeneration promoting activity, a neuronal cell death promoting activity, and the like" (p. 8, lines 21-23). It is further unclear what variations are encompassed by SEQ ID NO: 1, etc. and SEQ ID NOS: 6, 8, 10, 12, 14, 16, 18, 20, etc., as etc. (i.e. an unspecified number of additional items) may include any amino acid changes or alterations at any position in SEQ ID NO: 1, as well as partial peptides of SEQ ID NO: 1, that retain an activity encompassing a neural cell death promoting activity and the like. The instant specification is silent on the specific alterations that distinguish SEQ ID NOS: 6, 8, 10, 12, 14, 16, 18, 20 from SEQ ID NO: 1, as all appear to encompass amino acid sequences of the same size and highly similar sequence to that of SEQ ID NO: 1, and are therefore not representative of the numerous variants encompassed by the claim. The prior art at the time of filing did not teach the large number of possible sequence variants of SEQ ID NO: 1 that retain biological activities substantially the same nature as that of human NIPK protein.

Bowie, et al. (Science, 247: 1306-10, 1990) provide notable insight into the lack of reasonable predictability for the mutation of any particular protein. Specifically, Bowie et al. explain that while many substitutions may be tolerated, in other cases substitutions may not be tolerated at all (e.g., 1306, col. 2, paragraph 2). Moreover, the significance of surface and buried amino acids while is not reasonably predictable either (pp. 1306-07), surface sites may not have any importance, but sometimes they are absolutely important due to binding (p. 1308), and predicting structure with reasonable predictability is generally limited to homologous proteins, but even that is difficult due to alignment problems (p. 1308). Bowie continues: it is not reasonably predictable that any particular amino acid change, deletion, or addition would provide a functional molecule with similar activity, and only painstaking analysis would provide such information for any particular change (e.g., pp. 1309-10). These observations have been further supported by the findings of Skolnick et al. (TIBTECH 18:34-39, 2000), stating: "Knowing a protein's structure does not necessarily tell you its function" (Box 2, p. 36), noting that "alternatives are needed to assign the biochemical function of the 30-50% of proteins whose function cannot be assigned by any current methods" (second column, p. 37).

Hence, the nature of the invention is not reasonably predictable for any of the various possible sequence variants and their encoded proteins claimed, due to the unpredictability of structure-function relationships. Moreover, given the lack of reasonable predictability between structure and function, the identification and subsequent analysis for biological activity of each variant protein would require further and undue experimentation.

For inhibition of gene expression, the specification contemplates using antisense molecules, stating: "The antisense polynucleotide having a complementary or substantially complementary base sequence to the base sequence of a polynucleotide encoding the protein or partial peptide used in the present invention e.g., DNA... of the present invention and capable of suppressing the expression of said DNA, but antisense DNA is preferred. The base sequence substantially complementary to the DNA of the present invention may include, for example, a base sequence having at least about 70% homology" (p. 26, lines 7-17). Further stating that the antisense polynucleotide can be a double stranded ribozyme containing a part of the RNA encoding the protein of the present invention to suppress the *in vivo* function of the protein (p.

44, lines 30-34). However none of the examples in the specification are directed to the inhibition of human NIPK gene expression and no specific antisense molecules to the RNA encoding SEQ ID NO: 1 have been described.

The prior art has demonstrated that inhibition or RNA expression remains unpredictable and requires a significant degree of homology between the antisense and target RNA sequences. For example, the prior art of Branch (TIBS 23:45-50; 1998) teaches that antisense molecules and ribozymes are far more difficult to produce than was originally anticipated, and their ability to eliminate the function of a single gene has never been proven. Furthermore, a wide variety of unexpected non-antisense effects have come to light, complicating the use of antisense compounds (Abstract). The author further states that it is very difficult to predict what portions of an RNA molecule will be accessible *in vivo*, and that effective antisense molecules must be found empirically (first column, p. 49). Concluding, because non-antisense effects are not currently predictable, rules for rational design cannot be applied to the production of antisense drugs (first column, p. 50). The foregoing is especially pertinent to the instantly claimed method, encompassing numerous variants of SEQ ID NO: 1 having substantially the same amino acid sequence, thus, inviting a person of skill in the art to engage in further experimentation. Please note "case law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not to find out how to use it for themselves." *In re Gardner* 166 USPQ 138 (CCPA) 1970.

Given the foregoing issues, the nature of the invention is not reasonably predictable for the claimed method of inhibiting the expression of RNAs encoding variants of SEQ ID NO: 1, and would require further and undue experimentation.

The detail of the disclosure provided by Applicant, in view of the prior art, must encompass a wide knowledge, so that the person skilled in the art would be able to practice the invention as claimed by Applicants, without undue burden being imposed on such person of skill. This burden has not been met because it would require undue experimentation to demonstrate the inhibition of expression of the human NIPK gene by targeting its RNA (or its transcription machinery) by numerous variant antisense molecules.

The guidance provided by the specification amounts to an invitation for the skilled Artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification merely sets forth the amino acid sequence of human NIPK protein as SEQ ID NO: 1 and a base nucleotide sequence encoding the same, together with that of SEQ ID NOS: 6, 8, 10, 12, 14, 16, 18, 20, whose sequence structure relative to SEQ ID NO: 1 remains unclear.

Therefore, in view of the art recognized high level of unpredictability regarding establishment of protein structure/function relationships, and the inhibition of gene transcription and translation, together with the large quantity of research required to define these unpredictable variables, and the lack of guidance provided in the specification regarding the same, it is the position of the examiner that it would require undue experimentation for one of skill in the art to practice the scope of the invention as broadly claimed. Hence, absent a strong showing by Applicant, in the way of specific guidance and direction, and/or working examples demonstrating the same, such invention as claimed by Applicant is not enabled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Meyers et al. (U.S. Patent Application Publication No.: 2002/0034780; filed: Mar. 6, 2001).

To the extent that the instant claim encompasses an enabled method of screening for a compound or its salt that inhibits the expression of an RNA encoding a protein comprising the amino acid sequence set forth as SEQ ID NO: 1, said method comprising hybridizing an antisense molecule or ribozyme to RNA of a gene encoding a protein comprising the amino acid

sequence set forth as SEQ ID NO: 1, thereby inhibiting the function of said RNA, the following rejection over the prior art is applicable:

Meyers et al. teach human kinase nucleic acid sequences and proteins, and methods of using the same (Title and Abstract). Specifically disclosing in Figures 3A and 3B, the amino acid sequences of a human kinase protein (SEQ ID NO: 8), and its corresponding nucleotide sequence (SEQ ID NO: 9), the protein having 100% identity to the instantly claimed SEQ ID NO: 1. The kinase encoded by SEQ ID NO: 8 (also referred to as 13302 protein kinase [¶ 0062]), was found to be similar to rat NIPK neuronal cell-death-inducible putative kinase [¶ 0098]. Meyers et al additionally provide screening methods for identifying a compound that modulates the activity of the kinase protein as well as identifying a compound that modulates the expression of the kinase gene [¶¶ 0022-0024], wherein the compound or agent is a nucleic acid molecule having a nucleotide sequence that is antisense to the coding strand of the kinase mRNA or the kinase gene [¶ 0019]. The antisense nucleic acid molecules, are described as "molecules that are complementary to a sense nucleic acid encoding a protein, e.g., complementary to the coding strand of a double-stranded cDNA molecule, or complementary to an mRNA sequence. Accordingly, an antisense nucleic acid can hydrogen bond to a sense nucleic acid. The antisense nucleic acid can be complementary to an entire kinase coding strand, or to only a portion thereof, e.g., all or part of the protein coding region (or open reading frame)" [¶ 0180].

Further teaching: "The invention also encompasses ribozymes, which are catalytic RNA molecules with ribonuclease activity that are capable of cleaving a single-stranded nucleic acid, such as an mRNA, to which they have a complementary region. Ribozymes (e.g., hammerhead ribozymes (described in Haselhoff and Gerlach (1988) Nature 334:585-591)) can be used to catalytically cleave kinase mRNA transcripts to thereby inhibit translation of kinase mRNA. A ribozyme having specificity for a kinase-encoding nucleic acid can be designed based upon the nucleotide sequence of a kinase cDNA disclosed herein e.g., SEQ ID NOS: 1, 3, 4, 6, 7, 9" [¶ 0185].

Therefore by teaching all the limitations of claim 15, Meyers et al. anticipate the instant invention as claimed.

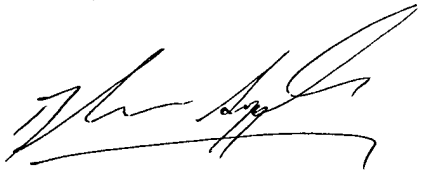
Conclusion

Claim 15 is not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is (571) 272-3311. The examiner can normally be reached on 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Fereydoun G. Sajjadi, Ph.D.
Examiner, A.U. 1633